Bio-Rad Laboratories
Whole Blood Immunosuppressant Controls
Summary of Safety and Effectiveness

K072721

1.0 **Submitter**

Bio-Rad Laboratories
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Irvine, California 92618-2017
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Contact Person

DEC 1 1 2007

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Telephone: (949) 598-1467

Date of Summary Preparation

September 13, 2007

2.0 **Device Identification**

Product Name:
- Lyphochek Whole Blood Immunosuppressant Control
- Abbott Immunosuppressant MCC

Common Name: Drug mixture control materials
Clinical toxicology control material.

Classification: Class I
Product Code: DIF
Regulation Number: 21 CFR 862.3280

3.0 **Device to Which Substantial Equivalence is Claimed**

Lyphochek Whole Blood Control
Bio-Rad Laboratories
Irvine, California 92618

510 (k) Number: K022041

4.0 **Description of Device**

Lyphochek Whole Blood Immunosuppressant Controls and Abbott Immunosuppressant MCC are both prepared from human whole blood, with added chemicals, and stabilizers.

5.0 Intended Use

Lyphochek Whole Blood Immunosuppressant Controls or Abbott Immunosuppressant MCC is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

1.0 COMPARISON OF THE NEW DEVICE WITH THE PREDICATE DEVICE

Whole Blood Immunosuppressant Controls claim substantial equivalence to the Lyphochek Whole Blood Control currently in commercial distribution (K022041).

Table 1: Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Lyphochek Whole Blood Immunosuppressant Controls Abbott Immunosuppressant MCC (New Device)		Bio-Rad Lyphochek Whole Blood Control (Predicate Device K022041)	
Similarities				
Intended Use	Lyphochek Whole Blood Immunosuppressant Control or Abbott Immunosuppressant-MCC is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.		Lyphochek Whole Blood Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	
Form	Lyophilized		Lyophilized	
Storage (Unopened)	2-8°C until expiration date		2-8°C until expiration date	
Open vial after Reconstitution (Refrigerated)	14 days at 2 to 8°C.		14 days at 2 to 8°C with the following exceptions: Red cell folate will be stable for 3 days at 2 to 8°C.	
Open vial after Reconstitution (Frozen)	30 days at –20 to –70°C.		30 days at –10 to –20°C.	
Differences				
Matrix	EDTA Whole blood		Citrated Whole blood	
Analytes	Cyclosporine Sirolimus Tacrolimus	Sirolimus Tacrolimus	Cyclosporine Sirolimus Tacrolimus	Red Cell Folate Lead Serotonin

6.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for this control. Product claims are as follows:

- Open vial Stability:
  - After reconstituting, all analytes will be stable for 14 days at 2 to 8°C or 30 days at –20 to -70°C.
- Shelf Life: 3 Years at 2 to 8°C

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

BioRad Laboratories Inc.
Diagnostics Group
c/o Ms. Elizabeth Platt
9500 Jeronimo Road
Irvine, CA 92618-2017

DEC 1 1 2007

Re: k072721
Trade/Device Name: Lyphochek Whole Blood Immunosuppressant Control
Regulation Number: 21 CFR§862.3280
Regulation Name: Clinical Toxicology Control Material
Regulatory Class: Class I, reserved
Product Code: DIF
Dated: September 21, 2007
Received: September 26, 2007

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072721

Device Name: **Lyphochek Whole Blood Immunosuppressant Control**

Indications For Use: **Lyphochek Whole Blood Immunosuppressant Controls is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.**

The following analytes are listed in the package insert:

- Sirolimus
- Tacrolimus
- Cyclosporine

Device Name: **Abbott Immunosuppressant MCC**

Indications For Use: **Abbott Immunosuppressant MCC is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.**

The following analytes are listed in the package insert:

- Sirolimus
- Tacrolimus

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072721